

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Douglas G. EVANS, et al.

Application No.: 10/633,254

Confirmation No.: 4792

Filed: August 1, 2003

Art Unit: 3773

For: SELF-ANCHORING SLING AND
INTRODUCER SYSTEM

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APPEAL BRIEF

This is an appeal of the Final Office Action mailed June 18, 2008, filed under 37 CFR § 1.191. This brief follows the notice of appeal filed October 20, 2008, and the subsequent Notice of Panel Decision from Pre-Appeal Brief Review, mailed January 14, 2009, which set a deadline of February 14, 2009 for the filing of an appeal brief. This brief is filed with a one-month extension of time to extend the deadline for response from February 14, 2009 to March 14, 2009, which is extended to the next succeeding business day, March 16, 2009, pursuant to 37 C.F.R. § 1.7(a). Accordingly, this brief is timely filed.

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST	1
II.	RELATED APPEALS AND INTERFERENCES	1
III.	STATUS OF CLAIMS	1
IV.	STATUS OF AMENDMENTS	1
V.	SUMMARY OF CLAIMED SUBJECT MATTER.....	2
	A. INDEPENDENT CLAIM 1 WITH EMBODIMENTS FROM CLAIMS DEPENDING THEREFROM.....	2
	B. INDEPENDENT CLAIM 132	3
VI.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL.....	4
	A. WHETHER CLAIMS 1-4, AND 120-123, 125-128, AND 131-132 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 OVER STASKIN IN VIEW OF RICHMOND?	4
	B. WHETHER CLAIM 124 IS UNPATENTABLE UNDER 35 U.S.C. § 103 OVER STASKIN IN VIEW OF RICHMOND, AND FURTHER IN VIEW OF SMITH?	4
	C. WHETHER CLAIMS 129 AND 130 ARE UNPATENTABLE UNDER 35 U.S.C. § 103 OVER STASKIN IN VIEW OF RICHMOND, AND FURTHER IN VIEW OF GELLMAN?	4
VII.	ARGUMENT.....	5
	A. REJECTION UNDER 35 U.S.C § 103(A) OVER STASKIN IN VIEW OF RICHMOND	5
	1. <i>Claims 1-3, 120-123, 125-128, and 131</i>	5
	a) Staskin fails to disclose a first arm pivotally mounted to the central portion	5
	b) Richmond fails to supply the features missing from Staskin.....	8
	c) Conclusion	8
	2. <i>Claim 4</i>	9
	3. <i>Claim 132</i>	10
	a) Staskin fails to disclose a shaft with a straight portion	11
	b) Staskin fails to disclose an elastically-biased latch portion in the handle.....	13
	c) Richmond fails to supply these missing features	14
	d) Conclusion	14
	B. REJECTION UNDER 35 U.S.C. § 103(A) OVER STASKIN IN VIEW OF RICHMOND, AND FURTHER IN VIEW OF SMITH	14
	C. REJECTION UNDER 35 U.S.C. § 103(A) OVER STASKIN IN VIEW OF RICHMOND, AND FURTHER IN VIEW OF GELLMAN	15
	D. CONCLUSION	15
	CLAIMS APPENDIX.....	i
	EVIDENCE APPENDIX.....	v
	RELATED PROCEEDINGS APPENDIX	vi

I. REAL PARTY IN INTEREST

The real party in interest is C. R. Bard, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant.

III. STATUS OF CLAIMS

Claims 1-4 and 120-132 are pending in this application.

Claims 1-4 and 120-132 are finally rejected and on appeal.

Claims 5-119 have been cancelled and are not on appeal.

IV. STATUS OF AMENDMENTS

Claims 35 and 36 were previously pending in the application, and were cancelled in the response to final Office Action, dated August 12, 2008. New claim 132 was filed in the response to final Office Action including the subject matter of independent claim 35 and dependent claim 36. Pursuant to 37 CFR § 1.116, Appellant believes new claim 132 presents the previously rejected claims 35 and 36 in a better form for consideration on appeal. In an Advisory Action, dated August 26, 2008, the amendments were entered and an explanation of how the new claim would be rejected was provided.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 1 with embodiments from claims depending therefrom

One embodiment of the system configured to support a female urethra, as claimed in independent claim 1, is shown generally in FIG. 13. As shown, the system includes an introducer needle 3, a handle 5, an implant member 1, and a connector 7. (p. 7, ¶ [0029]; p. 19, ¶ [0116]). Examples of each of these components is provided below.

As seen in FIG. 2, the introducer needle 3' has a first and second end 4, each having a flattened portion 13 with an opening 27 therethrough. (p.32, ¶ [0167]; p. 34, ¶ [0175]). Various cross-sectional profiles of the introducer needle may be employed. (p. 31, ¶ [0166]). With respect to dependent claim 24, one embodiment includes an introducer needle with oval cross section. (p. 75, ¶ [0339]). With respect to dependent claim 4, the introducer needle 3' may also include a flared section 47. FIGS. 14-16 illustrate examples of where the introducer needle has a flared section 47 having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the connector 7 in the given direction. (p. 30, ¶ [0161]; p. 42, ¶ [0203]).

The handle 5 can be removably joined to the introducer need 3, as depicted for example in FIGS. 1, 3, 4, and 5. As one example, the handle, seen in FIG. 4, has a latch mechanism 33 which engages the opening 27 in the flattened portion 13 of one end of the introducer needle 3. (p. 24, ¶ [0139]).

Various embodiments of the implant member may be seen, for example, in FIGS. 17-37. (p. 19, ¶ [0116]). With respect to dependent claim 29, the implant member includes an elongated body made of a flexible material that has a first end 89, a second end 89, and a support portion

81, 83a, 83b. (p. 42, ¶ [0204]). The support portion has an axis running along the length of the implant member, and has a plurality of slits 85 arranged along at least a portion of the axis 83a and 83b. (p.47, ¶ [0221]). With respect to dependent claim 30, the slits may be of V-shaped, semicircular, rectangular, oval, or arrowhead shaped. (FIGS. 18-20, 22, 24, 26; p. 47, ¶¶ [0222]-[0223]).

Embodiments of the connector may be found at, for example, FIGS. 7, 9-11, and 51. The connector joins the end of the implant member to the flattened portion of the end of the introducer needle. (p. 72, ¶ [0324]). The connector includes a central portion 51, 251, a first arm 55a, 255a, and a second arm 53a, 253a. (p. 36, ¶ [0184]). The first arm 55a, 255a is pivotally mounted (for example by living hinge 56, 256) to the central portion 51, 251 and has a first opening 61 at a first end. The second arm 53a, 253a is also pivotally mounted (for example by living hinge 56, 256) to the central portion 51, 251 and has a first projection 57, 257 therefrom. The first projection 57, 257 is positioned so that when the first arm 55a, 255a and the second arm 53a, 253a move together, the first projection 57, 257 is received in the first opening 61. (p. 36, ¶ [0184]; p. 38, ¶ [0192]; p. 41, ¶ [0202]).

B. Independent Claim 132

One embodiment of the introducer needle system configured to surgically introduce a urethral implant in a patient as claimed in Independent Claim 132 is shown, for example, in FIG. 5. The system includes an integrally formed introducer needle 3 including an elongated shaft connecting first and second flat spatulated sections 13. The shaft includes a straight portion 20 connected to a curved portion 22. (p. 172, ¶ [0172]). At least one of the spatulated sections 13 has a tip 15 or 16a, a constant width portion extending from the tip 13, and an opening 27 formed

in the constant width portion 13. (p. 22, ¶¶ [130]-[0131]). The first flat spatulated section 13 connects to the curved portion 22 by a flared section 47 having a cross-sectional profile that covers a cross-sectional profile of the first flat spatulated section. (p. 30, ¶ [0160]). The system further includes a handle 5 with a housing (6a and 6b) having an elongated portion with a distal end opening 25 dimensioned to receive and hold one of the flat spatulated sections 13. (p. 24, ¶ [0138]). The handle also includes an elastically-based latch portion 35 having a projection 39 dimensioned and disposed in the housing (6a and 6b) to engage the flat spatulated section inserted into the distal end opening 25 of the housing to secure the handle 5 to the introducer needle 3. (p. 24, ¶ [0139]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 1-4, and 120-123, 125-128, and 131-132 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond?
- B. Whether claim 124 is unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Smith?
- C. Whether claims 129 and 130 are unpatentable under 35 U.S.C. § 103 over Staskin in view of Richmond, and further in view of Gellman?

VII. ARGUMENT

A. Rejection under 35 U.S.C § 103(a) over Staskin in view of Richmond

Claims 1-4, 120-123, 125-128, and 131 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over USPN 6,612,977 to Staskin, et al. (hereinafter, “Staskin”), in view of USPN 4,509,516 to Richmond (hereinafter, “Richmond”). Appellant respectfully submits that the teachings of Staskin and Richmond are inadequate to support a *prima facie* case of obviousness, at least for the reasons set forth below.

1. Claims 1-3, 120-123, 125-128, and 131

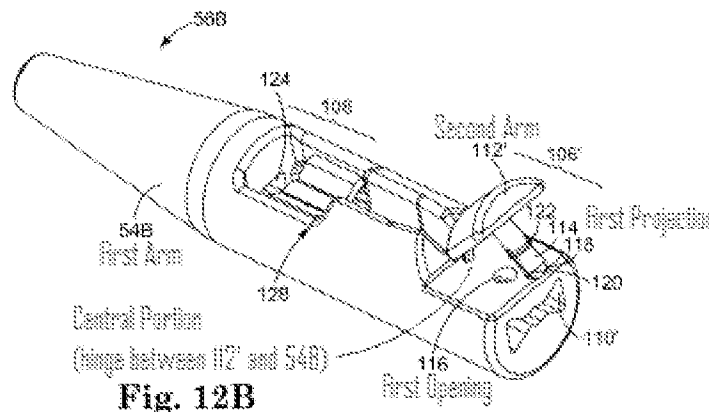
Independent claim 1 recites, *inter alia*, “a first arm pivotally mounted to the central portion and having a first opening at a first end; and a second arm pivotally mounted to the central portion.”

a) Staskin fails to disclose a first arm pivotally mounted to the central portion

The Office Action alleges that Staskin discloses the features of claim 1, including “a first arm (54B) pivotally mounted to the central portion and having a first opening (116).” (Office Action, p. 4). However, Staskin fails to disclose this limitation. First, the asserted first arm is *fixed*, as opposed to pivotally mounted, because it is the asserted second arm that is pivoted. However, even assuming *arguendo* that the first arm is pivotally mounted, Staskin fails to disclose a central portion. In other words, Staskin fails to disclose the first arm pivotally mounted to the central portion, because either the pivotal mount is not disclosed or the central

portion is not disclosed. Further, Appellant notes that Staskin does not appear to be enabled for the purposes of showing a pivotal mounting to a central portion as claimed.

Referring to Staskin FIG. 12B and the corresponding description of the interaction between the slot 110', opening 116, and snap-like element 112', it is clear that the surface of the alleged first arm 54B through which the opening 116 is disposed is *fixed*, as opposed to being *pivotally mounted*, as recited in independent claim 1. Staskin FIG. 12B is reproduced below and annotated with the alleged features asserted by the Office for the convenience of the Board.



Opening 116 is shown formed through a flat outer surface of a wall that defines one side of slot 110'. According to the Staskin specification, “one end of the sling 42, sheath 44 or sling assembly 46 is inserted into the slot 110' of the dilator 54B. With the end of the sling 42/sling assembly 46 properly positioned within the slot 110', the barb 114 of the snap-like element 112' is inserted into the opening 116 of the dilator 54B. The barb 114 is fully seated within the opening 116 when both ridges 120, 122 pass through the opening 116 of the dilator 54B.” (Staskin, 20:26-33). Accordingly, it is the snap-like element 112' (the asserted second arm) that is positioned relative to the dilator 54B (the asserted first arm), while the dilator 54B is fixed. Thus, contrary to the allegation in the Office Action, Staskin does not show or describe at least

the feature of “a first arm pivotally mounted to the central portion and having a first opening at a first end.”

However, assuming *arguendo* that “the hinge between 112’ and 54b allows relative pivotal motion between 112’ and the central portion, such that 112’ can also be ‘fixed,’ while the central portion pivots relative to the first arm,” as asserted in the Advisory Action, Staskin still fails to show or describe a pivotal connection to *a central portion*, as claimed.

According to the interpretation by the Office, Staskin discloses a central portion (the hinge between 112’ and 54B), a first arm (54B), and a second arm (112’). (Office Action, p. 4). In the Advisory Action, the Office appears to be asserting that the portion between 112’ and 54B is the central portion, as well as an alleged hinge to meet the pivotally mounted limitation. However, the alleged hinge cannot represent both features, as the first arm cannot be pivotally mounted to the pivotal mount. In other words, if the alleged hinge is the central portion, then the claimed feature of the first arm being “pivotally mounted” to “a central portion” would be read as the first arm being “pivotally mounted” to “a hinge creating the pivotal mount.” Therefore, if the asserted first arm is considered pivotally mounted, then there is no feature in Staskin that meets the central portion as required by claim 1.

Moreover, Appellants submit that claim 1 recites both a first arm pivotally mounted to the central portion and a second arm pivotally mounted to the central portion. It therefore follows that the central portion cannot be the “hinge creating the pivotal mount” because this arrangement only permits the alleged first and second arms to be pivotally mounted with respect to *each other* rather than the central portion as claimed.

Further, Appellant notes that there is no description or showing of a *hinge*, contrary to the allegation in the Advisory Action. As shown above, FIG. 12B of Staskin merely shows a “snap-like element 112” without disclosing any relationship between element 112 and dilator 54B. (Staskin, 20:9). Given this disclosure and the lack of representation within the figures, it is purely conjecture how the snap-like element 112’ couples to the dilator 54B. However, it is unlikely that the connection is by a hinge, as alleged. According to the specification, “the barb 114 of the snap-like element 112’ is inserted into the opening 116 of the dilator 54B.” (Staskin, 20:29-31). As one skilled in the art would recognize, a straight hinge would not permit the projection 114 to move fully into the opening 116 as the flat surface including the opening 116 would interfere with the path of the projection 114. Without any disclosure within the specification or the drawings, Staskin does not appear to be enabled for the purposes of showing a pivotal mounting to a central portion as claimed. (*See*, MPEP § 2121.04 (a picture must show all the claimed structural features and how they are put together in order to be sufficiently enabling prior art)).

b) Richmond fails to supply the features missing from Staskin

Richmond does not show or describe any connector joining the end of the implant member to the flattened portion of the second end of the introducer needle, much less the connector as recited in claim 1. Thus, Richmond does not cure the deficiencies of Staskin discussed above.

c) Conclusion

Appellant submits that a *prima facie* case of obviousness is not established at least because the asserted combination does not teach or suggest all of the limitations of independent

claim 1. Therefore, Appellant submits that independent claim 1, and claims 3-4, 120-123, 125-128, and 131 depending therefrom, are patentable over the asserted combination of Staskin and Richmond and request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

2. Claim 4

Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over to Staskin in view of Richmond. Appellant respectfully submits that the teachings of Staskin and Richmond are inadequate to support a *prima facie* case of obviousness, at least for the reasons set forth above, as claim 4 depends from patentable independent claim 1. Further, Staskin and Richmond fail to disclose the additional feature recited in dependent claim 4.

Claim 4, depending from claim 1, recites, *inter alia*, “wherein the introducer needle has a flared section having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the connector in the given direction.”

The Office Action asserts that Staskin discloses a needle with a flared section (tapered portion of 170 as seen on the left side of FIG. 16A) having a cross-sectional profile that is at least as large as the cross-sectional profile of the connector (56B of FIG. 12B). However, Appellant respectfully submits that this is a misinterpretation of Staskin. The asserted connector, the dilator of Staskin, is actually fitted over the needle end. Therefore, the Staskin dilator will always have a cross-sectional profile greater than the needle.

The asserted flared section 170 is a keying feature that is designed for complementary engagement to the appropriate ends of the dilator 54. (Staskin, 23:43-50). As discussed with respect to the dilator, the dilator includes an opening with an internal diameter generally

configured for convenient attachment to the needle, while the needle is positioned within the dilator. (Staskin, 18:66-19:2; 19:10; 20:49-50). Therefore, given that an internal diameter of the dilator fits over the needle, the asserted connector must be at least as large as the needle, while the cross-sectional profile of the dilator must be greater than the needle.

Richmond fails to supply this feature missing from Staskin as it does not show or describe *any* connector for the implant member to the introducer needle, as noted above.

Accordingly, Appellant submits that a *prima facie* case of obviousness is not established by the Office at least because the asserted combination does not teach or suggest all of the limitations of dependent claim 4. Therefore, Appellant submits that claim 4 is patentable over the asserted combination of Staskin and Richmond also for this reason and requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

3. Claim 132

Claim 132 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of Richmond. Appellant respectfully submits that the teachings of Staskin and Richmond are inadequate to support a *prima facie* case of obviousness, at least for the reasons set forth below.

Independent claim 132 recites, *inter alia*, “an integrally formed introducer needle including an elongated shaft connecting first and second flat spatulated sections. . . , the shaft including a straight portion connected to a curved portion. . . ; and a handle including. . . an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section inserted into the distal end opening of the housing to secure the handle to the introducer needle.”

a) Staskin fails to disclose a shaft with a straight portion

According to the comments in the Advisory Action, Staskin allegedly shows all of the features of claim 132 other than the constant width portion having an opening therethrough, at least in Staskin FIGS. 1, 1A, 4, 12A, 12B, 16A-16D, and 18A-18E. In particular, the Advisory Action notes that the claimed introducer needle is shown by Staskin component 60A or 60B, the flat spatulated sections of the needle are shown by component 126, and flared section connecting the flat spatulated section to the curved portion is shown by the tapered portion of component 170. However, no component is identified that corresponds to the claimed straight portion. Indeed, Appellant submits that Staskin fails to show or describe at least a straight portion connected to a curved portion, as claimed.

First, Staskin does not disclose a shaft with both straight and curved sections, instead stating the preference for a uniformly *curved* needle as follows:

In a preferred embodiment, the needle 60 may be substantially symmetric about a centerpoint, that is, the radius of curvature of the needle 60 may be substantially constant and either a handle or a dilator may be attached to either end of the needle 60.

(Staskin, 23:54-58).

Thus, Staskin describes a needle that is curved from end to end, including the sections that attach to either the handle or the dilator. Accordingly, the shaft, including a straight portion connected to a curved portion, is not shown or described by Staskin.

Further, even assuming *arguendo* that the first and second ends of the Staskin needle were not also intended to be curved with the rest of the needle, Staskin still does not show a

straight portion connected to a curved portion as claimed. This is due to the further recitation in claim 132 of the needle including an elongated shaft connecting first and second flat spatulated sections, and of a flared section that connects the flat spatulated section to the curved portion.

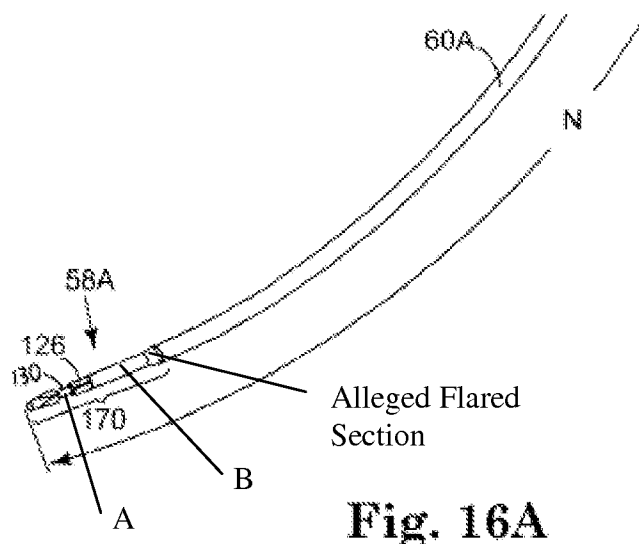


Fig. 16A

Referring to annotated FIG. 16A, above, Staskin discloses a needle 60 that is curved with a first end 58 and a second end 62. (Staskin, 23:6-7). If portion 126 is the flat spatulated portion, as alleged, then component A (recess 130) or component B (the section between the alleged flat spatulated section 126 and the alleged flared section) are the only options for the straight section of the shaft. Component A cannot be the claimed straight portion because it is not part of the shaft, which is recited as *connecting* the first and second flat spatulated sections. Therefore, the straight portion and the shaft must be on the same side of the flat spatulated section. Component B similarly cannot be straight portion as it is separated from the shaft by the flared section. Therefore, the flat spatulated section 126 and the flared section must be on the same side of the shaft 60A including the straight portion B. In other words, the straight portion B cannot be between the flat spatulated section 126 and the flared section.

Accordingly, Staskin does not show or describe at least a shaft including a straight portion connected to a curved portion.

b) Staskin fails to disclose an elastically-biased latch portion in the handle

With respect to the claimed handle, Appellant submits that Staskin fails to show or describe at least an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section. In particular, the Advisory Action identifies element 198 of alleged handle 64G as an elastically-biased latch portion having a projection. (*See*, Staskin, FIGS. 18A-B). However, the cross-sectional view of FIG. 18B shows that “push button assembly 198 comprises a button or knob-shaped component 202 that attaches to a yoke 204.” (Staskin, 25:7-9). “In particular, the yoke 204 is attached to the button 202 via snap tongs 206 that lock the button 202 and yoke 204 together.” (Staskin, 25:10-12). Thus, contrary to the assertion by the Office, there is no feature associated with element 198 that could constitute a “projection dimensioned and disposed in the housing to engage the flat spatulated section inserted into the distal end opening of the housing to secure the handle to the introducer needle,” as claimed. The only projections shown in Staskin with respect to the push button assembly 198 are the tongs 206, which lock the button to the yoke, rather than engage a flat spatulated section, as claimed.

Accordingly, Staskin does not show or describe at least an elastically-biased latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section.

c) Richmond fails to supply these missing features

Richmond fails to supply the missing features of a straight portion of the needle shaft or the elastically-biased latch portion of the handle. The asserted needle shown and described by Richmond is a “rod 11 which, in plan [*sic*] view, has the shape of an arc of a circle of large diameter.” (Richmond, 2:49-50). Further, the handle, shown and described by Richmond, includes cooperating threaded portions, rather than a elastically-biased latch portion. (*See, e.g.*, Richmond, FIGS. 1-3).

d) Conclusion

Accordingly, Appellant submits that a *prima facie* case of obviousness is not established at least because the asserted combination does not teach or suggest all of the limitations of independent claim 132. Therefore, Appellant submits that independent claim 132 is patentable over the asserted combination of Staskin and Richmond and request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

B. Rejection under 35 U.S.C. § 103(a) over Staskin in view of Richmond, and further in view of Smith

Claim 124 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of Richmond, and further in view of Smith. As discussed above, Staskin and Richmond fail to disclose features of independent claim 1, in which claim 124 depends. Smith does not provide the missing features. Smith is directed to a tapered I-beam surgical needle and therefore does not show or describe any features concerning a connector for an introducer needle. Therefore, for at least this reason, claim 124 is patentable over the asserted combination, and

Appellant requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

C. Rejection under 35 U.S.C. § 103(a) over Staskin in view of Richmond, and further in view of Gellman

Claims 129-130 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Staskin in view of Richmond, and further in view of Gellman. As discussed above, Staskin and Richmond fail to disclose features of independent claim 1, from which claims 129-130 depend. Gellman does not provide the missing features. Gellman is directed to a medical sling and does not show or describe any features concerning a connector for an introducer needle. Therefore, for at least this reason, claims 129-130 are patentable over the asserted combination, and Appellant requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

D. Conclusion

Claims 1-4, and 120-132 subject to this appeal are patentable for at least the reasons as set forth herein. Favorable action is solicited and a finding of patentability of claims 1-4, and 120-132 is respectfully requested.

Dated: March 16, 2009

Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously Presented) A system configured to support a female urethra, comprising:

an introducer needle having a first end and a second end, each said end having a

flattened portion with an opening therethrough;

a handle having a latch mechanism which engages the opening in the flattened

portion of the first end of the introducer needle;

an implant member having an end; and

a connector joining the end of the implant member to the flattened portion of the

second end of the introducer needle, wherein said connector comprises:

a central portion;

a first arm pivotally mounted to the central portion and having a first

opening at a first end; and

a second arm pivotally mounted to the central portion and having a first

projection therefrom, the first projection being positioned so that

when the first arm and the second arm move together, the first

projection is received in the first opening.

2. (Previously Presented) A system according to claim 1, wherein at least a portion of the introducer needle is curved and symmetrical.

3. (Previously Presented) A system according to claim 1, wherein the flattened portion of the first end differs in at least one of size and shape from the flattened portion of the second end.

4. (Original) The system according to claim 1, wherein the introducer needle has a flared section having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the connector in the given direction.

5-119. (Canceled).

120. (Previously Presented) A system according to claim 1, wherein said introducer needle has a rounded tip.

121. (Previously Presented) A system according to claim 1, wherein said introducer needle has an asymmetric shape.

122. (Previously Presented) A system according to claim 1, wherein each of said flattened portions has a tip, and the tip of the first flattened portion has a first configuration and the tip of the second flattened portion has a second configuration that is different from the first configuration.

123. (Previously Presented) A system according to claim 1, wherein said introducer needle has an arcuate shape.

124. (Previously Presented) A system according to claim 1, wherein at least a portion of said introducer needle has an oval cross section.

125. (Previously Presented) A system according to claim 1, wherein at least a portion of said introducer needle has a circular cross-section.

126. (Previously Presented) A system according to claim 1, wherein said implant member comprises:

a central portion having a first end and a second end;

a first arm joined to the first end; and

a second arm joined to the second end.

127. (Previously Presented) A system according to claim 126, wherein the first and second arms have a plurality of openings running therethrough.

128. (Previously Presented) A system according to claim 127, wherein the opening are arranged in a two-dimensional pattern.

129. (Previously Presented) A system according to claim 1, wherein the implant member comprises an elongated body made of a flexible material having a first end, a second end, and a support portion, the support portion having an axis running along the length of the implant member, the support portion having a plurality of slits arranged along at least a portion of the axis.

130. (Previously Presented) A system according to claim 129, wherein the slits are selected from the group consisting of V-shaped, semicircular, rectangular, oval, and arrowhead shaped.

131. (Previously Presented) A system according to claim 126, wherein each of the first and second ends has an opening therein.

132. (Previously Presented) An introducer needle system configured to surgically introduce a urethral implant in a patient, comprising:

an integrally formed introducer needle including an elongated shaft connecting first and second flat spatulated sections, at least one of said spatulated sections having a tip, a constant width portion extending from the tip, and an opening formed in the constant width portion, the shaft including a straight portion connected to a curved portion, the first flat spatulated section connected to the curved portion by a flared section having a cross-sectional profile that covers a cross-sectional profile of the first flat spatulated section; and

a handle including a housing having an elongated portion with a distal end opening dimensioned to receive and hold one of said flat spatulated sections, and an elastically-based latch portion having a projection dimensioned and disposed in the housing to engage the flat spatulated section inserted into the distal end opening of the housing to secure the handle to the introducer needle.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

Appellant is not aware of any proceedings.